K033244

OCT 16 2003

GE Medical Systems
P.O. Box 414, W-400
Milwaukee, WI 53201 USA

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
Tel. (262) 544-3894
Summary prepared: 5 September 2003

Identification of Product: Digital Fluoroscopic Imaging System
Classification Name: Fluoroscopic X-ray system – 21 CFR 892.1650
Manufacturer: GE Medical Systems Europe
283, rue de la Minière
78530 Buc Cedex, France
Distributed by: GE Medical Systems, Milwaukee, WI

Marketed Devices: The GE Medical System's Innova 4100, with a new Tilt table option for patient positioning, for diagnostic fluoroscopic imaging is substantially equivalent to *Siemens Axiom Artis (K021021).* This opinion is based on the information contained in the comparison table (Attachment 3), and the product data sheets (Attachment 4 & 5).

Device Description: The new tilt table is offered as an option for Innova 4100, in place of the existing Omega V table, which is part of the Innova 4100 system already cleared under K023178.

Materials: All construction and materials are compliant with UL 2601 and IEC 60601-1.

Design: There are hardware and software redundancies to prevent from single point failures that could cause unintended motion.

Energy Source: 480 VAC 50/60Hz.

Indications for Use: The Digital Fluoroscopic Imaging System with tilt table option is indicated for use in generating fluoroscopic images of human anatomy for diagnostic and intervention angiography procedures in both normal and tilted condition of patient. This

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2003

GE Medical Systems
% Mr. Donald James Sherratt
Medical Stream Director
Intertek Testing Services
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K033244
Trade/Device Name: Model Innova 4100
with Tilt Table Option
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified
fluoroscopic x-ray system
Regulatory Class: II
Product Code: 90 MQB
Dated: October 6, 2003
Received: October 7, 2003

Dear Mr. Sherratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K033244

Device Name: **Digital Fluoroscopic Imaging System – Innova 4100 with optional Tilt Table**

Indications for Use

The **Digital Fluoroscopic Imaging System** is indicated for use in diagnostic and interventional angiographic procedures of human anatomy. It is intended to replace image intensifier fluoroscopic systems in all diagnostic or interventionnal procedures. This device is not intended for mammography applications.

The new tilt table will support performing procedures like CO_2 studies, Venography.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033244